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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,008	08/07/2006	Toshiharu Suzuki	3749-0112PUS1	7226

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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1649

NOTIFICATION DATE	DELIVERY MODE
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05/04/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/577,008	Applicant(s) SUZUKI ET AL.	
	Examiner Olga N. Chernyshev	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6 and 10-19 is/are pending in the application.
- 4a) Of the above claim(s) 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6, 10-13 and 16-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>sequence alignment</u> |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 10, 2009 has been entered.

Response to Amendment

2. Claims 6, 10, 12 and 13 have been amended, claims 1-4 cancelled and claims 17-19 added as requested in the amendment filed on April 10, 2009. Following the amendment, claims 6 and 10-19 are pending in the instant application.

3. Claims 14-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 17, 2008.

4. Claims 6, 10-13 and 16-19 are under examination in the instant office action.

5. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

6. Applicant's arguments filed on April 10, 2009 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 12-13 and 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 12 is vague and ambiguous for reciting limitation “peptide consisting of any one of SEQ ID NOS: 4 to 12 or 14 to 17 and one or more additional amino acids of SEQ ID NO: 1”. Specifically, the structure of the recited peptide cannot be ascertained from the claim or the instant specification and therefore, the metes and bounds of the claimed subject matter are indefinite.

10. Also, claim 12 recites “a ratio” of the peptides and it is not clear if the ratio is between any two of the peptides of SEQ ID NOS: 4 to 12 or 14-17 or any other ratio.

11. Further, claim 12 appears to be adding an additional step to the steps of claim 10; however, the meaning of limitation “ratio [...] is used as an indicator for diagnosing Alzheimer’s disease” is vague and indefinite. Clarification of what specific ratio values or another use of the ratio stand as a diagnostic measure is required.

12. Claims 13 and 19 are indefinite as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the final step that leads to identification of a therapeutic agent for AD as stated in the preamble of the claims. Also, claims 13 and 19 recite determination of relative amounts or changes in molecular species without a clear comparison step or reference to a point of

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comparison. For example, “a decrease in the amount of the peptide [...] caused by said agent to be screened” seems to be only possible in comparison to the same procedure in the absence of the agent. Finally, the claim recites change in the molecular species of the peptide without any indication as what stands for the change to be determined. Is it increase, decrease of the certain species, the amounts of these certain species or both?

13. Claim 18 does not make sense. The claim expressly requires comparison of the amounts of “a first peptide” to the amount of “a high-molecular weight peptide” defined as a cleavage product of SEQ ID NO: 1 and being of higher MW than the first peptide. Claim 18 depends from claim 10, which does not recite “a first peptide” or any peptides defined by molecular weight, therefore the relationship between critical elements and steps in the claim is missing.

14. Finally, claims 12, 13 and 19 depend from claim 6 which is not limited to one peptide; therefore any reference to species of “the peptide” wherein the peptides of SEQ ID NOS 4-12 and 14-17 appear to be species of each other because of the minimal difference in their structure renders the claimed subject matter vague and indefinite.

15. Claim 17 is indefinite for being dependent from indefinite claim.

16. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

17. Claims 10-13 and 16 stand rejected under 35 U.S.C. 112, first paragraph, for reasons of record as applied to claims 7-13 in section 16 of Paper mailed on July 07, 2008. The

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specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

At p. 8 of the Response, Applicant traverses the rejection by stating that the instant specification is fully enabled for the methods as claimed and refers to pages 15-21, Example 11 and figure 19. Applicant's arguments have been fully considered but are not persuasive for the following reasons.

The information presented at the passages cited by Applicant is limited to general description of prophetic diagnostic protocols and experimental data limited to detection of full-length of the polypeptide of SEQ ID NO: 1, Alcadin α , Alca α , colocalized with APP in brain tissue of AD patients (Fig. 3 and 4) and generation of different species of Alca α by transfected HEK293 cells. The instant specification and Applicant's Response do not present any explanation or scientific reasoning as why or how these data support the instant diagnostic method as currently claimed. There is no disclosure of relevance of the *in vitro* model used or reference to art-recognized technique to establish that the instant claimed method can be practiced without undue experimentation by one skilled in the art.

18. Claims 13 and 17-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement essentially for reasons of record as applied to claim 13 in section 16 of Paper mailed on July 07, 2008. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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Applicant traverses the rejection by reference to pp. 21-23, Examples 9, 12 and figures 20-23, see Response at pp. 8-9. Applicant's arguments have been given careful consideration but are unpersuasive for reasons that follow.

Claims 13 and 17-19 are directed to methods of screening for therapeutic agents for Alzheimer's disease. As an initial matter, the final step that leads to a meaningful result - identification of a useful therapeutic agent - is missing from the claims, see reasons of record in sections 12-14 of the instant office action. Further, as fully explained in the previous communications of record, the instant specification fails to present any factual evidence or a line of scientific reasoning to support a conclusion that the processing of the instant Alca polypeptide, as recited in the claimed methods, has any relevance to the etiology of Alzheimer's disease. There is also no record of any particular agent identified by the claimed method, which stands for lack of working examples to support the claimed invention.

The statutory language of 112, first paragraph mandates satisfaction of the enablement requirement: in exchange for a patent, an applicant must enable reproduction and use of his invention. Further, the court decision of *Genentec, Inc. v. Novo Nordisk*, 42 USPQ 2d 100,(CAFC 1997), makes it clear that: "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". In the instant case, the instant specification is not enabled for the method claimed. It would require a significant amount of undue experimentation and essentially making an inventive contribution for the worker of skill in the art to research and discover how to practice Applicant's invention as currently claimed.

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Claim Rejections - 35 USC § 102

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20. Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Sonderegger et al., 2002, reference BA of IDS submitted on 02/27/2007.

Claim 6 is directed to peptides consisting essentially of an amino acid sequence represented by any one of SEQ ID NOS: 4 to 12 or 14 to 17. Document of Soderegger et al. discloses polypeptide with 100% sequence identity to the polypeptide 820-838 of SEQ ID NO: 1, see copy of the sequence alignment attached to the instant office action. Since peptides of SEQ ID NOS: 4 to 12 or 14 to 17 represent various overlapping fragments of SEQ ID NO: 1, starting at position 815 and ending at position 855 and further due to use of an open language to describe the struture of the claimed peptides – “consisting essentially of” – the peptide described by Soderegger et al. fully meets the limitations of the claimed products and the instant invention is anticipated.

Applicant is advised that if it is Applicant's desire to claim short specific fragments of SEQ ID NO: 1, specifically peptides of SEQ ID NOS: 4-12 and 14-17, then the claim should be drawn to "an isolated peptide consisting of the amino acid sequence selected from the group consisting of SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 14, SEQ ID NO: 15, SEQ ID NO: 16 and SEQ ID NO: 17".

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Conclusion

21. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Olga N. Chernyshev, Ph.D.

April 28, 2009

/Olga N. Chernyshev/
Primary Examiner, Art Unit 1649